Congress of the United States
Washington, DC 20515

Stephen M. Hahn, M.D.
Commissioner
United States Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20903

August 17, 2020

Dear Commissioner Hahn,

I write to convey my concerns about the potential use of an emergency use authorization for a coronavirus vaccine without proper safety guardrails and to request additional information related to the guidelines and standards by which the FDA is assessing new coronavirus vaccines.

Our nation has witnessed vaccine developers accomplish in a matter of months what has historically taken two to four years. New technology, international collaboration, and innovative investment have spurred unprecedented progress towards a coronavirus vaccine. As trials advance from Phase III into a potential Emergency Use Authorization (EUA) approval process during this time, we have a responsibility to ensure that safety and efficacy are not compromised. Furthermore, we have a responsibility to the public to provide clarity and confidence in any upcoming vaccine. A recent Gallup poll indicates that 1 in every 3 Americans would not get a free, FDA-approved vaccine if it was ready today.[1] Without a clear understanding of the process, standards, and system by which these vaccines are vetted, public confidence will continue to fall and jeopardize immunization efforts.

While the FDA has assured the public that vaccine candidates will be reviewed and assessed using the same standards as previous vaccines, the agency has not yet shared these standards with the public. Given the reduction in testing time for each phase and the combined phase approach several candidates have adopted, the public also needs to understand how traditional standards will be applied to these candidates using more modern techniques. The introduction of new types of vaccines, like messenger RNA vaccines, into clinical trials places additional pressure on the FDA to communicate how these never before tested vaccines will be assessed in the short term for an infectious disease. The rapid turnaround time expected by President Trump, who has indicated that a vaccine may be available before the November 3 election[2], further hastens testing time for these new vaccines and stands in direct contrast to the guidance provided by public health experts. Here, I want to emphasize how important it will be to determine approval based on evidence alone.

Guidelines for the Data Safety Monitoring Board (DSMB) suggest that the board would be able to assess the data at any point and pause trials if the Board determines a vaccine to be unsafe or

[1] https://news.gallup.com/poll/317018/one-three-americans-not-covid-vaccine.aspx

[2] https://www.reuters.com/article/us-health-coronavirus-trump-vaccine/trump-says-coronavirus-vaccine-possible-before-nov-3-idUSKCN25221Q

ineffective.[3] Given the hundreds of vaccines under review, including the 6 candidates included in Operation Warp Speed, the public needs to understand how these boards are going to equitably and comprehensively audit the candidates within the two month turnaround time in which an EUA is anticipated.

Finally, if there is an expedited development process, we need to understand what monitoring measures will be put into place after the EUA is awarded to ensure the continued safety of our citizens. Since the FDA does not have the luxury of approving a vaccine after the typical 1-4 years of Phase III testing[4], we need to ensure that mechanisms are established to identify and address side effects across all populations.

I respectfully request that you respond to the following questions directly to my office by September 1, 2020:

- Does the FDA plan to utilize an EUA for one or more coronavirus vaccines? If so, how many vaccines is the FDA expecting to receive EUA authorization?
- How does the FDA plan to demonstrate to the American people that the vaccines will be approved on the basis of evidence and not influenced by politics?
- If an EUA is used, how exactly does the FDA plan to shorten a typical approval time of one to two years into one to two months[5] without sacrificing quality and safety?
- What parameters is the FDA using to assess the vaccine candidates? How do these parameters differ from those adhered to during assessments of traditional candidates?
- How does the FDA plan to assess vaccine approaches which have never been developed and scaled before, such as the mRNA candidates, in a one to two-month time period?
- What process will the Data Safety Monitoring Board follow in order to assess and/or audit all vaccine candidates equally and effectively?
- What monitoring measures will be put in place at the national and subnational levels to ensure there are no adverse side effects from any COVID-19 vaccine?
- How will the FDA be working with other agencies like DoD to ensure proper production and deployment and distribution of a vaccine?

Thank you for your consideration of this request.

Sincerely,

Andy Kim

Andy Kim
Member of Congress

[3] https://www.fda.gov/media/75398/download
[4] https://www.fda.gov/patients/drug-development-process/step-3-clinical-research
[5] https://www.weforum.org/agenda/2020/04/why-a-coronavirus-vaccine-takes-over-a-year-to-produce-and-why-that-is-incredibly-fast/